ISRCTN65289389 https://doi.org/10.1186/ISRCTN65289389

Cracked nipples colonized with Staphylococcus aureus: a randomised treatment trial

Submission date	Recruitment status	[_] Prospectively registered
09/12/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/12/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/10/2014	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Judith Lumley

Contact details
Director
Centre for the Study of Mothers' and Children's Health
La Trobe University
251 Faraday Street
Carlton
Australia
VIC 3053

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Research Ethics Number (La Trobe University): 00/124

Study information

Scientific Title

Acronym
ROBIn (Reduction of Breast Infection) Trial

Study objectives
The aim of our study was to prevent mastitis in breastfeeding women with cracked nipples colonised with S. aureus. The hypothesis was that a course of antibiotics would reduce mastitis in breastfeeding women with cracked nipples colonized with S. aureus. Participating women were randomised to receive a seven-day course of either an oral antibiotic (flucloxacillin) or identical placebo capsules.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Mastitis (prevention of) in lactating women

Interventions
Women with nipple swab positive for Staphylococcus aureus are randomised to receive a seven-day course of:
1. Flucloxacillin 500 mg qid, or
2. Identical placebo capsules

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Flucloxacillin

Primary outcome measure
Incidence of mastitis in each group in the week following recruitment.

Secondary outcome measures
Nipple healing, nipple pain.

Overall study start date
01/11/2001

Completion date
30/11/2002

Eligibility

Key inclusion criteria
1. Breastfeeding women with at least one damaged nipple
2. English-speaking
3. Live in Melbourne
4. Not allergic to penicillin

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
10

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/11/2001

Date of final enrolment
30/11/2002

Locations

Countries of recruitment
Australia

Study participating centre
Director
Carlton
Australia
VIC 3053

Sponsor information

Organisation
La Trobe University (Australia)

Sponsor details
Faculty of Health Sciences
Melbourne
Australia
VIC 3086
+61 (0)3 9479 3583
lhs@latrobe.edu.au

Sponsor type
University/education

Website
http://www.latrobe.edu.au/health/healthsci_schoolcent.html

ROR
https://ror.org/01rxfrp27

Funder(s)

Funder type
Research council

Funder Name
Medical Research Foundation for Women and Babies, Melbourne (Australia)

Funder Name

Australian National Health and Medical Research Council Public Health scholarship (Australia)

Funder Name
Postgraduate grant, Faculty of Health Sciences, La Trobe University (Australia)

Funder Name
Antibiotics provided by CSL Ltd

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	16/09/2004		Yes	No